WE CLAIM:

1. A multiple unit dosage form comprising multiple units, each unit comprising: at least one core having an outer surface;

a first coating layer surrounding at least a portion of the outer surface of the core and having an outer surface, the coating layer including one or both of one or more active pharmaceutical ingredients and one or more rate controlling polymers; and

an outer layer, the outer layer comprising a material that is one or both of elastic and compressible.

2. The multiple unit dosage form of claim 1, wherein the core includes the one or more rate controlling polymers.

3. The multiple unit dosage form of claim 1, wherein the core includes the one or more active pharmaceutical ingredients.

4. The multiple unit dosage form of claim 1, wherein the core includes one or more of sugar, a non-pareil seed, microcrystalline cellulose, celphere, sand silicon dioxide, glass, plastic, polystyrene, hydroxypropyl methylcellulose.

5. The multiple unit dosage form of claim 4, wherein the sugar comprises one or more of glucose, mannitol, lactose, xylitol, dextrose, and sucrose.

6. The multiple unit dosage form of claim 1, wherein the core comprises one or more of an insoluble material, a soluble material, and a swellable material.

7. The multiple unit dosage form of claim 1, wherein the rate controlling polymer comprises one or more of cellulosic polymers, methacrylic acid polymers, and waxes.

8. The multiple unit dosage form of claim 1, wherein the rate controlling polymer comprises one or more of ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, and hydroxyethylcellulose, hydroxypropylmethyl phthalate, cellulose acetate phthalate, and cellulose acetate trimellitate.

9. The multiple unit dosage form of claim 1, wherein the one or more active pharmaceutical ingredients comprises one or more of antidepressants, antidiabetics,

antiulcers, analgesics, antihypertensives, antibiotics, antipsychotics, antineoplastics, antimuscarinics, diuretics, antimigraine agents, antivirals, anti-inflammatory agents, sedatives, antihistaminics, antiparasitic agents, antiepileptics and lipid lowering agents.

10. The multiple unit dosage form of claim 1, wherein the one or more active pharmaceutical ingredients comprise one or more of enalapril, captopril, benazepril, lisinopril, ranitidine, famotidine, ranitidine bismuth citrate, diltiazem, propranolol, verapamil, nifedipine, acyclovir, ciprofloxacin, simvastatin, atorvastatin, lovastatin, venlafaxine, citalopram, paroxetine, selegiline, midazolam, fluoxetine, acarbose, buspirone, nimesulide, captopril, nabumetone, glimepiride, glipizide, etodolac, nefazodone and their pharmaceutically acceptable salts.

11. The multiple unit dosage form of claim 1, wherein the one or more active pharmaceutical ingredients comprises one or both of glipizide and venlafaxine or their salts.

12. The multiple unit dosage form of claim 1, wherein the core includes the rate controlling polymer and the active pharmaceutical ingredient.

13. The multiple unit dosage form of claim 1, wherein the first coating layer further includes the active pharmaceutical ingredient.

14. The multiple unit dosage form of claim 1, wherein the first coating layer includes the one or more active pharmaceutical ingredients.

15. The multiple unit dosage form of claim 1, further comprising one or more additional layers, wherein the additional layers are positioned between (a) one or more of the core and the first coating layer and (b) surrounding at least a portion of the first coating layer,

wherein the one or more additional layers comprise one or more of a seal coat, a film forming layer, a rate controlling polymer, and an active pharmaceutical ingredient.

16. The multiple unit dosage form of claim 15, wherein the seal coat comprises one or more of hydroxypropyl methylcellulose, polyvinyl pyrrolidone, and methacrylic acid copolymers.

17. The multiple unit dosage form of claim 15, wherein the film forming layer includes one or more of ethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methyl cellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropyl methyl phthalate, cellulose acetate, cellulose acetate trimelliatate, cellulose acetate phthalate, waxes, polyethylene glycol, and methacrylic acid polymers.

18. The multiple unit dosage form of claim 1, wherein the material in the outer layer comprises one or more wax materials.

19. The multiple unit dosage form of claim 18, wherein the wax material comprises one or more polyethylene glycols (PEGs).

20. The multiple unit dosage form of claim 19, wherein the one or more polyethylene glycols (PEGs) differ by molecular weight.

21. The multiple unit dosage form of claim 20, wherein the polyethylene glycol (PEG) comprises one or more of PEG 600, PEG 4000, PEG 6000, PEG 8000, and PEG 20000.

22. The multiple unit dosage form of claim 19, wherein the waxy material comprises from about 1% to about 15% by weight of the total dosage form weight.

23. The multiple unit dosage form of claim 19, wherein the waxy material comprises from about 1% to about 100% by weight of the weight of the core and the first coating layer.

24. The multiple unit dosage form of claim 19, wherein the waxy material is applied to each unit as a solution, suspension, dispersion, or hot melt technique.

25. The multiple unit dosage form of claim 24, wherein the solution, suspension, or dispersion is made using a solvent,

wherein the solvent comprises one or more of methylene chloride, isopropyl alcohol, acetone, methanol, ethanol, and water.

26. The multiple unit dosage form of claim 1, wherein the active pharmaceutical ingredient comprises glipizide and is in one or both of the core and the first coating layer.

27. The multiple unit dosage form of claim 26, further comprising a buffering agent with the glipizide in one or both of the core and the first coating layer.

28. The multiple unit dosage form of claim 27, wherein the buffering agent comprises one or more of dibasic sodium phosphate, sodium ascorbate, meglumine, sodium citrate trimethanolamine, sodium hydroxide, potassium hydroxide, calcium hydroxide, magnesium hydroxide, ammonia, tertiary sodium phosphate, diethanolamine, ethylenediamine, and L-lysine.

29. The multiple unit dosage form of claim 1, wherein one or more of the core and the first coating layer includes one or more pharmaceutically acceptable excipients.

30. The multiple unit dosage form of claim 29, wherein the pharmaceutically acceptable excipients includes surfactants, binders, diluents, disintegrants, lubricants, glidants, plasticizers, stabilizers, and coloring agents.

31. The multiple unit dosage form of claim 30, wherein the surfactants include one or more of a non-ionic surfactant, an ionic surfactant, mono fatty acid esters of polyoxyethylene sorbitan, polyoxyethylene (20) sorbitan monooleate (Tween 80), polyoxyethylene (20) sorbitan monostearate (Tween 60), polyoxyethylene (20) sorbitan monolaurate (Tween 20), an anionic surfactant, sodium lauryl sulfate, polyoxyethylene castor oil derivative, polyoxyethyleneglycerol triiricinoleate castor oil, polyoxyl 35 castor oil, Cremophor EL, and Vitamin E TPGS, d-alpha-tocopheryl polyethylene glycol 1000 succinate, polyethoxylated fatty acids and their derivatives, polyethylene glycol 400 distearate, polyethylene glycol - 20 dioleate, polyethylene glycol 4–150 mono dilaurate, polyethylene glycol –20 glyceryl stearate, alcohol – oil transesterification products, polyethylene glycol – 6 corn oil, polyglycerized fatty acids, polyglyceryl – 6 pentaoleate, propylene glycol fatty acid esters, propylene glycol monocaprylate, mono and diglycerides, glyceryl ricinoleate, sterol and sterol derivatives, sorbitan fatty acid esters and their derivatives, polyethylene glycol – 20 sorbitan monooleate and sorbitan monolaurate, polyethylene glycol alkyl ether or phenols, polyethylene glycol – 20 cetyl ether, polyethylene glycol – 10 – 100 nonyl phenol, sugar esters, sucrose monopalmitate,

polyoxyethylene – polyoxypropylene block copolymers, poloxamer, sodium caproate, sodium glycocholate, soy lecithin, sodium stearyl fumarate, propylene glycol alginate, octyl sulfosuccinate disodium, and palmitoyl carnitine.

32. The multiple unit dosage form of claim 30, wherein the binders includes one or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth, sodium alginate, and propylene glycol.

33. The multiple unit dosage form of claim 30, wherein the diluents include one or more of calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic, calcium sulfate, microcrystalline cellulose, silicified microcrystalline cellulose, cellulose powdered, dextrates, dextrins, dextrose excipients, fructose, kaolin, lactitol, lactose, mannitol, sorbitol, starch, starch pregelatinized, sucrose, sugar compressible, and sugar confectioners.

34. The multiple unit dosage form of claim 30, wherein the disintegrants include one or more of starch, croscarmellose, crospovidone, and sodium starch glycolate.

35. The multiple unit dosage form of claim 30, wherein the lubricants and glidants include one or more of colloidal anhydrous silica, stearic acid, magnesium stearate, calcium stearate, talc, hydrogenated caster oil, sucrose esters of fatty acid, microcrystalline wax, yellow beeswax, and white beeswax.

36. The multiple unit dosage form of claim 30, wherein the plasticizers include one or more of polyethylene glycol, triethyl citrate, triacetin, diethyl phthalate, and dibutyl sebacate and the stabilizers include one or more of antioxidants, buffers, and acids.

37. The multiple unit dosage form of claim 1, wherein the dosage form comprises a tablet.

38. The multiple unit dosage form of claim 37, wherein the tablet further includes one or more pharmaceutically acceptable excipients around the individual units.

39. The multiple unit dosage form of claim 1, wherein the dosage form comprises a capsule.

40. The multiple unit dosage form of claim 1, wherein the active pharmaceutical ingredients comprise one or more of atorvastatin and amlodipine, metformin and glipizide, simvastatin and ramipril, simvastatin and amlodipine, metformin XL and glipizide XL, ramipril and atorvastatin, ramipril and amlodipine, metformin XL and glimiperide, fosinopril and amlodipine.

41. A process for the preparation of a multiple unit dosage form, the process comprising:

providing at least one core having an outer surface;

forming a coated core by applying one or more coating layers to the core such that the one or more coating layers surround at least a portion of the outer surface of the core or the coating layers;

forming an individual unit by applying a waxy material to the coated core to form a wax layer;

combining one or more units to form a multiple unit dosage form,

wherein one or both of the core and the coating layers includes one or more rate controlling polymers and active pharmaceutical ingredients.

42. The process of claim 41, further comprising applying one or both of a seal layer or a film forming layer between the core and the coating layer, between the one or more coating layers, and between the one or more coating layers and the wax layer.

43. The process of claim 41, wherein the waxy material comprises one or more polyethylene glycols (PEGs) of one or more molecular weights.

44. The process of claim 43, wherein the polyethylene glycols (PEG) comprise one or more of PEG 600, PEG 4000, PEG 6000, PEG 8000, and PEG 20000.

45. The process of claim 41, wherein the waxy material comprises from about 1% to about 15% by weight of the total dosage form weight.

46. The process of claim 41, wherein the waxy material comprises from about 1% to about 100% by weight of the weight of the core and the one or more coating layers.

47. The process of claim 41, wherein applying the waxy material comprises applying a coating of a solid waxy material by using a hot melt technique.

48. The process of claim 41, wherein applying the waxy material comprises applying a coating of waxy material by using as one or more of a solution, a suspension, and a dispersion.

49. The process of claim 48, wherein the solution or the suspension is prepared in a solvent.

50. The process of claim 49, wherein the solvent is selected from one or more of methylene chloride, isopropyl alcohol, acetone, methanol, ethanol, and water.

51. The process of claim 41, wherein the core comprises an inert core.

52. The process of claim 41, wherein the core comprises one or more pharmaceutically acceptable excipients.

53. The process of claim 41, wherein the core comprises one or more active pharmaceutical ingredients.

54. The process of claim 41, wherein the one or more active pharmaceutical ingredients comprises one or more of antidepressants, antidiabetics, antiulcers, analgesics, antihypertensives, antibiotics, antipsychotics, antineoplastics, antimuscarinics, diuretics, antimigraine agents, antivirals, anti-inflammatory agents, sedatives, antihistaminics, antiparasitic agents, antiepileptics and lipid lowering agents.

55. The process of claim 41, wherein the one or more active pharmaceutical ingredients comprise one or more of enalapril, captopril, benazepril, lisinopril, ranitidine, famotidine, ranitidine bismuth citrate, diltiazem, propranolol, verapamil, nifedipine, acyclovir, ciprofloxacin, simvastatin, atorvastatin, lovastatin, venlafaxine, citalopram, paroxetine, selegiline, midazolam, fluoxetine, acarbose, buspirone, nimesulide, captopril, nabumetone, glimepiride, glipizide, etodolac, nefazodone and their pharmaceutically acceptable salts.

56. The process of claim 41, wherein the core is prepared by extrusion-spheronization.

57. The process of claim 56, wherein the extrusion-spheronization process comprises:

granulating an inert core material with or without other pharmaceutical excipients with a binder solution to form a wet mass;

passing the wet mass through an extruder to form extrudates; and

spheronizing the extrudates.

58. The process of claim 41, wherein the core is prepared by granulation.

59. The process of claim 58, wherein the granulation process comprises wetting a dry mix of core material with or without other pharmaceutical excipients with a binder solution.

60. The process of claim 41, wherein the units are prepared by coating the cores with active pharmaceutical ingredients and rate controlling polymers.

61. The process of claim 41, wherein the units are prepared by coating cores with a first layer comprising an active pharmaceutical ingredient and a second outer layer comprising a rate controlling polymer.

62. The process of claim 41, further comprising applying a seal coat or a film forming layer between the core and the subsequent layers or between a layer comprising an active pharmaceutical ingredient and a layer comprising a release rate controlling polymer

63. The process of claim 41, wherein the rate controlling polymer comprises one or more of cellulosic polymers, methacrylic acid polymers, waxes, ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose, carboxymethylcellulose, hydroxymethylcellulose, and hydroxyethylcellulose, hydroxypropylmethyl phthalate, cellulose acetate phthalate, and cellulose acetate trimellitate.

64. The process of claim 41, wherein the active pharmaceutical ingredient comprises venlafaxine.

65. The process of claim 41, wherein the active pharmaceutical ingredient comprises glipizide.

66. The process of claim 41, wherein the dosage form comprises a tablet.

67. The process of claim 41, wherein the dosage form comprises a capsule.

68. A method for preparing a modified release multiple unit dosage form, the method comprising:

providing a core having a coating, wherein one or both of the core and the coating include one or more of rate controlling polymers and active pharmaceutical ingredients;

forming individual units by coating the coated core with a coating material that is one or both of compressible and elastic; and

forming the dosage form by combining one or more individual units.

69. The method of claim 68, wherein combining one or more individual units comprises compressing the individual units into a tablet

70. The method of claim 68, wherein combining one or more individual units comprises filling the individual units into a capsule or sachet.

71. The method of claim 68, wherein the coating material comprises a waxy material.

72. The method of claim 68, wherein the coating material comprises a polyethylene glycol.

73. A method of treating a medical condition, the method comprising administering a multiple unit dosage form for oral ingestion, each unit comprising a core, one or more layers surrounding the core, and an outer layer, wherein

the core comprises one or more of a pharmaceutically acceptable excipients, an active pharmaceutical ingredient, and a rate controlling polymer,

the one or more layers comprises one or more of a pharmaceutically acceptable excipient, an active pharmaceutical ingredient, a rate controlling polymer, a sealing layer, and a film forming layer, and

the outer layer comprises a material that is one or both of compressible and elastic to partially or completely absorb a force exerted in forming the multiple unit dosage form by combining the units.

74. The method of claim 73, wherein the material of the outer layer comprises a waxy material.

75. The method of claim 74, wherein the waxy material comprises one or more polyethylene glycols of different molecular weights.

76. The method of claim 73, wherein the dosage form comprises a tablet.

77. The method of claim 73, wherein the dosage form comprises a capsule.

78. A multiple unit dosage form comprising multiple units, each unit comprising:

at least one core having an outer surface and comprising one or more one active pharmaceutical ingredients; and

a coating layer surrounding at least a portion of the outer surface of the core, having an outer surface and comprising a waxy material.

79. The multiple unit dosage form of claim 78, wherein the waxy material comprises one or more polyethylene glycols of different molecular weights.

80. The multiple unit dosage form of claim 78, wherein the dosage form comprises a tablet.

81. The multiple unit dosage form of claim 78, wherein the dosage form comprises a capsule.

82. A combination drug, multiple unit dosage form comprising:

first units; and

second units,

each first unit comprising at least one core having an outer surface, a first coating layer surrounding at least a portion of the outer surface of the core and having an outer surface, and an outer layer surrounding at least a portion of an outer surface of the first coating layer, the first coating layer including a first active pharmaceutical ingredient,

each second unit comprising at least one core having an outer surface, a first coating layer surrounding at least a portion of the outer surface of the core and having an outer surface, and an outer layer surrounding at least a portion of an outer surface of the first coating layer, the first coating layer including a second active pharmaceutical ingredient,

wherein one or both of the cores and the coating layers comprise a rate controlling polymer, and

one or both of the outer layers comprise a waxy material,.

83. The combination drug, multiple unit dosage form of claim 82, wherein the waxy material comprises one or more polyethylene glycols.

84. The combination drug, multiple unit dosage form of claim 82, wherein the dosage form comprises a tablet.

84. The combination drug, multiple unit dosage form of claim 82, wherein the dosage form comprises a capsule.

85. A multiple unit dosage form comprising multiple units, each unit comprising:

at least one core having an outer surface;

a first coating layer surrounding at least a portion of the outer surface of the core and having an outer surface, the coating layer including glipizide or its pharmaceutically acceptable salt and optionally one or more rate controlling polymers.

86. The multiple unit dosage form of claim 85, wherein the pharmaceutically acceptable salt comprises one or more of mineral acid salts, organic acid salts, and organosulphonic acid salts.

87. The multiple unit dosage form of claim 85, wherein the core includes one or more of sugar, a non-pareil seed, microcrystalline cellulose, celphere, sand silicon dioxide, glass, plastic, polystyrene, hydroxypropyl methylcellulose.

88. The multiple unit dosage form of claim 87, wherein the sugar comprises one or more of glucose, mannitol, lactose, xylitol, dextrose, and sucrose.

89. The multiple unit dosage form of claim 85, wherein the core comprises one or more of an insoluble material, a soluble material, and a swellable material.

90. The multiple unit dosage form of claim 85, wherein the rate controlling polymer comprises one or more of cellulosic polymers, methacrylic acid polymers, waxes, ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose,

carboxymethylcellulose, hydroxymethylcellulose, and hydroxyethylcellulose, hydroxypropylmethyl phthalate, cellulose acetate phthalate, and cellulose acetate trimellitate.

91. The multiple unit dosage form of claim 85, wherein the core includes rate controlling polymer and glipizide.

92. The multiple unit dosage form of claim 85, further comprising one or more additional layers, wherein the additional layers are positioned between (a) one or more of the core and the first coating layer and (b) surrounding at least a portion of the first coating layer,

wherein the one or more additional layers comprise one or more of a seal coat, a film forming layer, a rate controlling polymer, and an active pharmaceutical ingredient.

93. The multiple unit dosage form of claim 92, wherein the seal coat comprises one or more of hydroxypropyl methylcellulose, polyvinyl pyrrolidone, and methacrylic acid copolymers and the film forming layer comprises one or more of ethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methyl cellulose, carboxymethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropyl methyl phthalate, cellulose acetate, cellulose acetate trimelliatate, cellulose acetate phthalate, waxes, polyethylene glycol, and methacrylic acid polymers.

94. The multiple unit dosage form of claim 85, further comprising an outer layer, the outer layer comprising a material that is one or both of elastic and compressible.

95. The multiple unit dosage form of claim 94, wherein the material in the outer layer comprises one or more wax materials.

96. The multiple unit dosage form of claim 95, wherein the wax material comprises one or more polyethylene glycols (PEGs).

97. The multiple unit dosage form of claim 85, further comprising a buffering agent with the glipizide in the first coating layer.

98. The multiple unit dosage form 97, wherein the buffering agent comprises one or more of dibasic sodium phosphate, sodium ascorbate, meglumine, sodium citrate trimethanolamine, sodium hydroxide, potassium hydroxide, calcium hydroxide,

magnesium hydroxide, ammonia, tertiary sodium phosphate, diethanolamine, ethylenediamine, and L-lysine.

99. The multiple unit dosage form of claim 85, wherein the dosage form comprises a tablet.

100. The multiple unit dosage form of claim 85, wherein the dosage form comprises a capsule.

101. A modified release multiple unit system comprising units of glipizide, wherein the units comprise:

an inert core;

a drug layer surrounding the inert core, the drug layer comprising glipizide; and

a rate controlling polymer layer surrounding the drug layer.

102. The modified release multiple unit system of claim 101, wherein the system comprises a tablet.

103. The modified release multiple unit system of claim 101, wherein the system comprises a capsule.

104. A modified release multiple unit system comprising units of glipizide wherein the units comprise:

an inert core;

a drug layer surrounding the inert core;

a rate controlling polymer layer surrounding the drug layer; and

a waxy layer surrounding the drug layer.

105. The modified release multiple unit system of claim 104, wherein the units can be compressed into tablet, or filled into a capsule or a sachet; without affecting the desired release characteristics of drug.

106. The modified release multiple unit system of claim 104, wherein the system comprises a tablet.

107. The modified release multiple unit system of claim 104, wherein the system comprises a capsule.

108. A modified release multiple unit system comprising units of venlafaxine, wherein the units comprise:

an inert core;

a drug layer surrounding the inert core; and

a rate controlling polymer layer surrounding the drug layer.

109. The modified release multiple unit system of claim 108, wherein the system comprises a tablet.

110. A modified release multiple unit system comprising units of venlafaxine wherein the units comprise:

an inert core;

a drug layer surrounding the inert core;

a rate controlling polymer layer surrounding the drug layer; and

a waxy layer surrounding the rate controlling polymer layer.

111. The modified release multiple unit system of claim 110, wherein the units can be compressed into tablet without affecting the desired release characteristics of drug.

112. A modified release multiple unit system comprising units of a drug wherein the units comprise:

an inert core;

a drug layer surrounding the inert core;

a rate controlling polymer layer surrounding the drug layer; and

a waxy layer surrounding the rate controlling polymer layer.

113. The modified release multiple unit system of claim 112, wherein the units can be compressed into tablet, or filled in capsule or sachet; without affecting the desired release characteristics of drug.

114. A process for the preparation of a modified release multiple unit system of a drug, the process comprising the steps of:

coating inert pellets with a drug and rate controlling polymer layer;

coating with a waxy layer;

optionally blending with pharmaceutically acceptable excipients;

compressing into a tablet, or filling into a capsule or a sachet of suitable size.

115. A process for the preparation of a modified release multiple unit system of drug, the process comprising the steps of:

coating inert pellets with a drug and rate controlling polymer layer;

coating with a waxy layer;

optionally blending with pharmaceutically acceptable excipients;

compressing into tablet of suitable size.

116. The process of claim 115, wherein the drug comprises venlafaxine or a pharmaceutically acceptable salt.

117. A process for the preparation of modified release multiple unit system of drug comprising the steps of:

coating drug containing cores with a rate controlling polymer layer;

coating the rate controlling polymer layer with a waxy layer;

optionally blending with pharmaceutically acceptable excipients; and

compressing into tablet, or filling into capsule or sachet of suitable size.